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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,637

06/01/2006

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Q76459

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23373 7590 04/21/2011
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EXAMINER

TCHERKASSKAYA, OLGA V

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

04/21/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/562,637</p>	<p>Applicant(s) UENO, RYUJI</p>	
	<p>Examiner OLGA V. TCHERKASSKAYA</p>	<p>Art Unit 1615</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 April 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

Continuation of 5. Applicant's reply has overcome the following rejection(s): (1) The 35 U.S.C. 103(a) rejection of claims 1, 6-16 and 18-21, 24, 25, 27 and 28 over Ueno et al. (U.S. Pat. No. 6,583,174) is hereby withdrawn. (2) The 35 U.S.C. 103(a) rejection of claims 1, 6-16 and 18-28 over Ueno et al. (WO 03/030912) is hereby withdrawn. (3) Applicant's argument that Ueno et al. (U.S. Pat. No. 6,583,174) and Ueno et al. (WO 03/030912) do not constitute a prior art under 35 U.S.C. 102(a) and 102(e) for the purpose of this obviousness rejection was found to be persuasive.

Continuation of 11. does NOT place the application in condition for allowance because: Claims 1, 6-16 and 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (hereinafter "Ueno") (EP 0979651). This rejection is maintained.

Applicant's arguments have been fully considered but were not found to be persuasive.

With respect to the Applicant's arguments regarding the tautomeric ratio, it is the position of the Examiner that the molecular mechanism of biological activity does not impart patentability to an otherwise obvious invention. Moreover, in the instant case there is no sufficient evidence supporting

- the high medical efficiency of one molecular form of bicyclic prostaglandin over another molecular form, and/or
- molecular mechanism of drug activity in vivo based on experiments in vitro or that involving an animal model.

With respect to the targeted delivery of the active compound (to avoid acidic conditions) or diminishing side effects (such as nausea) during the drug administration, it is position of the Examiner that these are the basic reasons for coating pharmaceutical compositions for:

- improving efficiency of the drug administration,
- simplifying drug consumption, and
- providing commercial appeal to the product.

It is also position of the Examiner that effect of aggressive acidic condition (pH 2 in stomach) during the oral drug administration constitutes a major challenge to the pharmaceutical market that is resolved on regular basis through the enteric coatings of tablets, pills, capsules, etc. Applicant arguments were not held persuasive